

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent application of:

Applicant(s): Horace W. Hale et al.  
Serial No: 10/651,871  
Filing Date: August 29, 2003  
Title: FACET IMPLANT  
Examiner: Annette R. Reimers  
Art Unit: 3733  
Docket No. HORA.P0101US

**APPEAL BRIEF**

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The undersigned submits this corrected brief for the Board's consideration of the appeal of the Examiner's decision, mailed March 7, 2007, finally rejecting claims 1-20 and 41-58 of the above-identified application. A payment covering the filing fee was included with the original brief filed on April 18, 2007.

**I. Real Party in Interest**

The real party in interest in the present appeal is **Gerraspine A.G.**, a corporation of Switzerland having a place of business at Rorschacher Str. 292, 9016 St. Gallen, Switzerland, the assignee of the present application.

## **II. Related Appeals and Interferences**

Although the application does not claim priority from the present application or parent thereof, a notice of appeal and appeal brief have been filed for U.S. Application No. 10/762,008, which involves similar legal issues and cited art and therefore may be affected by or have a bearing on the Board's decision in the pending appeal.

## **III. Status of Claims**

Claims 1-20 and 41-58 are pending. Claims 1-20 and 41-58 stand finally rejected and are the subject of this appeal. A correct copy of the claims 1-20 and 41-58 is reproduced in the Claims Appendix.

## **IV. Status of Amendments**

No amendments have been filed after the final rejection of claims 1-20 and 41-58, which was mailed on March 7, 2007.

## **V. Summary of Claimed Subject Matter<sup>1</sup>**

The claimed subject matter relates generally to prostheses for treating spinal pathologies, and more specifically to a system and method for treating articulating surfaces of facet joints. [1/8-10]<sup>2</sup>

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<sup>1</sup> This summary is presented in compliance with the requirements of 37 C.F.R. §41.37(c)(1)(v), mandating a concise explanation involved in the appeal. Nothing contained in this summary is intended to change the specific language of the claims described, nor is the language in the summary to be construed so as to limit the scope of the claims in any way.

<sup>2</sup> Page number/line number(s) of the specification.

**The Invention as Defined in the Rejected Claims**

**Claim 1:** A facet implant comprises a superior implant (102) having an articulating surface (108) and a fixation surface (110). The superior implant (102) is configured for placement on a superior articular facet. [6/4-17; Figs. 5A-C; various shapes and features of the superior implant (102) are described throughout pages 5-10 of the specification]. The facet implant also comprises an inferior implant (104) having an articulating surface (112) and a fixation surface (114). [7/33 – 8/5; Figs. 5A-C; various shapes and features of the inferior implant (104) are described throughout pages 5-10 of the specification]. The inferior implant (104) is configured for placement on an inferior articular facet and for interacting with a translaminar fixation mechanism (106) such that the articulating surface (108) of the superior implant (102) and the articulating surface (112) of the inferior implant (104) are configured to interact. [7/33 – 8/5; 8/31-32; Figs. 5A-C]. The facet implant also comprises a translaminar fixation mechanism (106) for securing the inferior implant (104) to the inferior articular facet. [10/1-4; Figs. 5A-C; claim 2].

**Claim 14:** A facet implant comprises a superior implant (102) having a fixation surface (110) and a generally curved articulating surface (108). The superior implant (102) is configured for placement on a resurfaced articulating surface of a superior articular facet. [6/4-17; Figs. 5A-C; various shapes and features of the superior implant (102) are described throughout pages 5-10 of the specification]. The facet implant also comprises an inferior implant (104) having a fixation surface (114) and a generally convex articulating surface (112). The inferior implant (104) is configured for placement on a resurfaced articulating surface of an inferior articular facet, such that the generally

curved articulating surface (108) of the superior implant (102) and the generally convex articulating surface (112) of the inferior implant (104) interact. [7/33 – 8/5; Figs. 5A-C; various shapes and features of the inferior implant (104) are described throughout pages 5-10 of the specification].

**Claim 20:** A facet implant comprises a superior implant (102) having a fixation surface (110) and a generally curved articulating surface (108). The superior implant (102) is configured for placement on a resurfaced articulating surface of a superior articular facet. [6/4-17; Figs. 5A-C; various shapes and features of the superior implant (102) are described throughout pages 5-10 of the specification]. The facet implant also comprises an inferior implant (104) having a fixation surface (114) and a generally convex articulating surface (112). The inferior implant (104) is configured for placement on a resurfaced articulating surface of an inferior articular facet and for interacting with a translaminal screw. [7/33 – 8/5; 8/31-32; Figs. 5A-C; various shapes and features of the inferior implant (104) are described throughout pages 5-10 of the specification]. The articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact. [7/33 – 8/5; Figs. 5A-C]. The facet implant also comprises a translaminal fixation mechanism for securing the inferior implant to the inferior articular facet. [10/1-4; Figs. 5A-C].

**Claim 41:** A facet implant comprises superior implant means for providing an artificial articulating surface on a superior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the superior implant means is the superior implant (102). [6/4-17; Figs. 5A-C various shapes and features of the superior implant (102) are described throughout pages 5-10 of the specification]. The facet

implant also comprises inferior implant means for providing an artificial articulating surface on an inferior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the inferior implant means is the inferior implant (104). [7/33 – 8/5; 8/31-32; Figs. 5A-C; various shapes and features of the inferior implant (104) are described throughout pages 5-10 of the specification]. The facet implant further comprises means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6 and the structure that corresponds to the means is the translaminal fixation mechanism (106), which is described more specifically in the specification as a screw, a bolt or a pin. [10/1-9; Figs. 5A-C; claim 2].

**Claim 47:** A facet implant comprises superior implant means for providing an artificial articulating surface on a superior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the superior implant means is the superior implant (102). [6/4-17; Figs. 5A-C; various shapes and features of the superior implant (102) are described throughout pages 5-10 of the specification]. The superior implant means has a fixation surface (110) and a generally curved articulating surface (108). [6/4-17; Figs. 5A-C]. The superior implant means is further configured for placement on a resurfaced articulating surface of a superior articular facet such that the superior implant means primarily contacts only the articulating surface of the superior articulating facet. [[6/4-17; Figs. 5A-C]. The facet implant also comprises inferior implant means for providing an artificial articulating surface on an inferior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the inferior implant means is the inferior implant (104). [7/33 – 8/5; 8/31-32; Figs. 5A-C;

various shapes and features of the inferior implant (104) are described throughout pages 5-10 of the specification]. The inferior implant means has a fixation surface (114) and a generally convex articulating surface (112). The inferior implant means is further configured for placement on a resurfaced articulating surface of an inferior articular facet such that the inferior implant means primarily contacts only the articulating surface of the inferior articulating facet. [7/33 – 8/5; 8/31-32; Figs. 5A-C]. The generally curved articulating surface (108) of the superior implant means and the generally convex articulating surface (112) of the inferior implant means are configured for articulating interaction. [7/33 – 8/5; 8/31-32; Figs. 5A-C].

**Claim 53:** A facet implant comprises superior implant means for providing an artificial articulating surface on a superior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the superior implant means is the superior implant (102). [6/4-17; Figs. 5A-C; various shapes and features of the superior implant (102) are described throughout pages 5-10 of the specification]. The superior implant means has a fixation surface (110) and a generally convex articulating surface (108). [6/4-17; 7/9-17; Figs. 5A-C]. The superior implant means is further configured for placement on a specifically prepared articulating surface of a superior articular facet such that the superior implant means primarily contacts only the articulating surface of the superior articulating facet. [6/4-17; Figs. 5A-C]. The facet implant also comprises inferior implant means for providing an artificial articulating surface on an inferior articular facet. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the inferior implant means is the inferior implant (104). [7/33 – 8/5; 8/31-32; Figs. 5A-C; various shapes and features of the inferior implant (104) are

described throughout pages 5-10 of the specification]. The inferior implant means has a fixation surface (114) and a generally curved articulating surface (112). The inferior implant means is further configured for placement on a specifically prepared articulating surface of an inferior articular facet such that the inferior implant means primarily contacts only the articulating surface of the inferior articulating facet. [7/9 – 8/5; 8/31-32; Figs. 5A-C]. The generally convex articulating surface (108) of the superior implant means and the generally curved articulating surface (112) of the inferior implant means are configured for articulating interaction. [7/9 – 8/5; 8/31-32; Figs. 5A-C].

#### **VI. Grounds of Rejection to Be Reviewed on Appeal**

A. Claims 1, 2, 4-6, 8-11, 14-17, 19, 20, 41-44, 46-49, 51-55, 57 and 58 stand finally rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2002/0151895 (**Soboleski**).

B. Claims 3, 12 and 13 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over **Soboleski**.

C. Claims 7, 18, 45, 50 and 56 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over **Soboleski** in view of U.S. Patent Publication 2005/0143818 (**Yuan**).

## VII. Argument<sup>3</sup>

The rejections advanced by the Examiner are improper and should be reversed for at least the following reasons.

### Background

Degenerative spinal diseases can involve articular surfaces only, but may also have a more invasive pathology including traumatic, infectious, tumorous or dysmorphic (spondylolisthesis, for example) effecting the destruction of all or part of the articular process. [1/32 – 2/1]. Conventional treatments generally include some type of intervertebral stabilization, which may be spinal fusion, vertebral fixation, decompressive laminectomy, or spinal disc replacement. [2/6-14]. Spinal disc replacements, for example, provide a “space” between two vertebral bodies while preserving some motion but do not function to reduce the force on posterior joint facets. [2/14-17].

These conventional treatments have varying success rates and are limited in that none puts the spine in proper alignment or return the spine to a desired anatomy. [2/18-20]. In addition, stabilization techniques, by holding the vertebrae in a fixed position, permanently limit a person’s mobility. [2/20-22]. Indeed, even procedures utilizing motion devices not intended to limit mobility have a high incidence of spontaneous fusion. [2/20-24]. There is a need for an improved treatment for facet joint pathologies.

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<sup>3</sup> In the event the Examiner clarifies the rejections of any claims that have not been argued separately, Applicant reserves the right to argue separately such claims.



**A. Rejection of Claims 1, 2, 4-6, 8-11, 14-17, 19, 20, 41-44, 46-49, 51-55, 57 and 58 under 35 U.S.C. § 102(e)**

Claims 1, 2, 4-6, 8-11, 14-17, 19, 20, 41-44, 46-49, 51-55, 57 and 58 stand finally rejected as being anticipated by **Soboleski**. According to the examiner:

Soboleski et al. disclose a facet implant comprising a superior implant, 14, having an articulating surface and a fixation surface and configured for placement on a superior articular facet, a inferior implant, 16, having an articulating surface and a fixation surface and configured for placement on an inferior articular facet and for interacting with a translaminar fixation mechanism, wherein the articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact, and a translaminar fixation mechanism, at 19, for securing the inferior implant to the inferior articular facet (see figures 2 and 3A-3F and paragraph 0043). The superior implant and the inferior implant comprise a surface fixation mechanism, e.g. 54, 64, 68, 72, 74, 84 or 88 such as one or more pegs, one or more pips, ridges, or one or more screws (see figure 3A-3F paragraphs 0049-0052). Furthermore, Soboleski et al. teach the use of a an implant composed of at least one of cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, and TiAlN (see paragraph 0048).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Soboleski et al., which is capable of being used as claimed if one so desires to do so. In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

\* \* \* \*

Applicant's arguments filed December 08, 2006 have been fully considered, but they are not persuasive. Examiner understands applicant's point regarding the implant of Soboleski. However, applicant has not explicitly claimed that the superior and inferior implants are separate, i.e. neither integral nor monolithic. Therefore, distinct components 14 and 16, of Soboleski ,can be considered implants.<sup>4</sup>

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<sup>4</sup> Office Action dated March 7, 2007, pp. 2-3, 5.

The Examiner's rejections are improper and should be reversed. As discussed in detail below, the Examiner relies on two basic misconceptions to support the rejections:

**Misconception 1:** The "configured for" language in the claims does not impart any structural limitations to the claim elements; and

**Misconception 2:** *Soboleski* discloses a translaminar fixation mechanism.

***Claims 1, 2, 4-6 and 8-11***

Independent claim 1 recites a facet implant comprising a superior implant having an articulating surface and a fixation surface and being configured for placement on a superior articular facet; an inferior implant having an articulating surface and a fixation surface and being configured for placement on an inferior articular facet and for interacting with a translaminar fixation mechanism, whereby the articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact; and a **translaminar fixation mechanism** for securing the inferior implant to the inferior articular facet.

1. **Soboleski discloses only a single implant.**

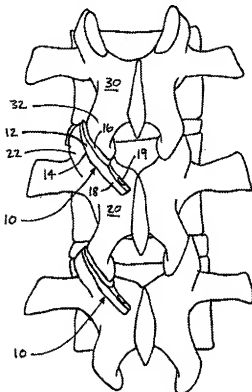
In rejecting independent claim 1, the Examiner relied on the misconceived notion that claim 1 recites functional statements that do not impose structural limitations on the claims that are "distinguishable over Soboleski et al., which is capable of being used as claimed if one so desires to so."<sup>5</sup> Whether the phrase "configured for" introduces structural limitations in a claim depends on the specific facts of the case. See, MPEP 2111.04. In this case, the phrase "the articulating surface of the superior implant and

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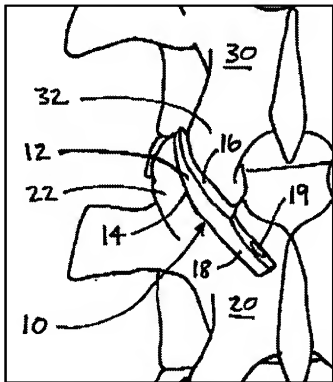
<sup>5</sup> Office Action dated March 7, 2007, p. 3.

the articulating surface of the inferior implant are configured to interact" ***at the very least*** requires that the superior implant and the inferior implant be elements capable of interacting with one another.

Thus, if for no other reason, ***Soboleski*** cannot anticipate independent claim 1 because ***Soboleski*** discloses only a single implant as shown below.



(Figure 2 of ***Soboleski***)



(Close-up view)

As ***Soboleski*** makes abundantly clear, the device of ***Soboleski*** is a single implant—not superior and inferior implants with surfaces capable of articulating with one another. Specifically, ***Soboleski*** discloses a facet cap 10 designed to act as a shim and create space between the superior and inferior facets on one side of a vertebra to correct asymmetry and treat scoliosis. While it may appear at first glance that elements 14 and 16 of ***Soboleski*** are separate implants, ***Soboleski*** leaves no

doubt that elements **14** and **16** are in fact opposing surfaces of a single implant. As described in **Soboleski**, the facet cap **10** has a shim portion **12** with two opposing surfaces, a lower surface **14** and an upper surface **16**.<sup>6</sup> In addition, the implant may also have an alignment portion having an extension or "tongue **18**, having an orifice **19** to accept a screw or the like which is driven into the cortex of the vertebral pedicle."<sup>7</sup>

Paragraphs 0042 and 0043 of **Soboleski** are reproduced below:

[0042] FIG. 1 shows a posterior view of a typical scoliotic spine, with asymmetry between left and right facet joints, and spinal curvature convex left. FIG. 2 shows the spine of FIG. 1 in which the asymmetry between left and right facet joints has been corrected with two spinal facet caps according to an embodiment of the present invention. As can be seen in FIG. 2, a spinal facet cap **10** according to the invention comprises a shim portion **12** which is implanted between the superior facet **22** of a first (lower) vertebra **20** and the corresponding inferior facet **32** of a second overlying vertebra **30**. The shim portion has two opposed surfaces, a first (lower) surface **14** engaging the superior articular surface of the superior facet **22**, and a second (upper) surface **16** engaging the inferior articular surface of the corresponding inferior facet **32**. The opposed surfaces of the shim portion of the spinal facet cap can be substantially planar, as shown in FIG. 2, or they can be formed (e.g., concave or convex) to receive and at least partially complement or parallel superior and inferior facet contours.

[0043] From FIG. 2 it will be appreciated that the shim portion of the spinal facet cap must be properly aligned or positioned in the facet joint, and that this alignment must be maintained. An alignment portion is provided for this purpose. The alignment portion can be provided numerous ways in accordance with the invention. For example, the alignment portion can comprise an extension or tongue **18**, having an orifice **19**, to accept a screw or the like which is driven into the cortex of the vertebral pedicle. The alignment portion can also comprise one or more facet hooks and/or a ridge or boss disposed along the perimeter or margin of the shim portion, to engage the superior and/or inferior facets. The alignment portion at least partially encompasses the superior and/or inferior facet(s).

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<sup>6</sup> **Soboleski**, paragraph 0042.

<sup>7</sup> **Soboleski**, paragraph 0043.

Independent claim 1 requires both a superior implant and an inferior implant, each having an articulating surface configured to interact with the articulating surface of the other. **Soboleski** discloses only a single implant. This deficiency of **Soboleski** was discussed in the Response to the Office Action Dated August 25, 2006. In response to this argument, the Examiner stated:

“applicant has not explicitly claimed that the superior and inferior implants are separate, i.e. neither integral nor monolithic. Therefore, distinct components 14 and 16 of Soboleski can be considered implants.”<sup>8</sup>

The Examiner's response not only mischaracterizes claim 1, but also demonstrates the Examiner's misreading of **Soboleski**. As explained to the Examiner, **Soboleski** unquestionably identifies elements **14** and **16** as surfaces on opposite sides of a single implant—**not as surfaces of superior and inferior implants configured to interact with one another:**

The shim portion has two opposed surfaces, a first (lower) surface 14 engaging the superior articular surface of the superior facet 22, and a second (upper) surface 16 engaging the inferior articular surface of the corresponding inferior facet 32.<sup>9</sup>

**Soboleski** could not be more clear. The Examiner's position is wholly without merit. **Soboleski** does not anticipate claim 1.

2. **Soboleski** does not disclose a translaminar fixation mechanism.

Even if **Soboleski** were found to disclose both a superior implant and an inferior implant—which it does not—**Soboleski** still fails to disclose a translaminar fixation mechanism as recited in claim 1. According to the Examiner, **Soboleski** includes:

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<sup>8</sup> Office Action dated March 7, 2007, p. 5.

<sup>9</sup> **Soboleski**, paragraph 0042.

a translaminar fixation mechanism, at 19, for securing the inferior implant to the inferior articular facet (see figures 2 and 3A-3F and paragraph 0043).<sup>10</sup>

The Examiner is wrong for multiple reasons. First and foremost, element **19** of

**Soboleski** is an orifice; and the orifice **19** of **Soboleski** is designed to accept a pedicle screw—not a translaminar screw:

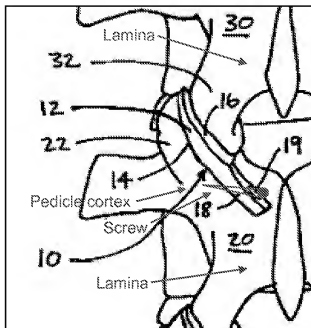
For example, the alignment portion can comprise an extension or tongue 18, having an orifice 19, to accept a screw or the like which is driven into the cortex of the vertebral pedicle.<sup>11</sup>

Second, **Soboleski** mentions that a screw may be passed through the orifice 19 and driven into the pedicle cortex. Such a screw would not be a translaminar fixation mechanism—it would not pass through the lamina. This deficiency of **Soboleski** was identified in the Response to the Office Action Dated August 25, 2006. The Examiner never substantively responded. To aid in the understanding of the differences between **Soboleski** and the claimed invention, Fig. 2 of **Soboleski** is reproduced below showing how a screw would be driven into the cortex of the pedicle, which is roughly located in part along the line pointing to the cap **10**.

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<sup>10</sup> Office Action dated March 7, 2007, p. 2.

<sup>11</sup> **Soboleski**, paragraph 0043.



(Soboleski with pedicle screw)

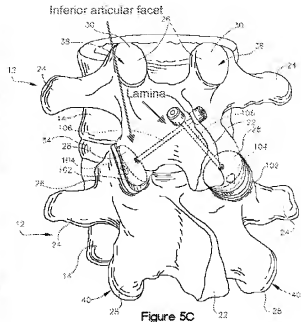


Figure 5C

(Translaminar fixation mechanism)

It is clear from the images above that the pedicle cortex screw mentioned in **Soboleski** cannot be a translaminar fixation mechanism. It is not understood how the implant of **Soboleski** could be fixed to an inferior articular facet using a fixation mechanism that passes through a lamina, and there is certainly no suggestion in **Soboleski** that the disclosed implant could be fixed to the inferior articular facet in such a manner.

Third, even if the pedicle cortex screw mentioned in **Soboleski** could satisfy the claim limitation of a translaminar fixation mechanism—which it cannot—**Soboleski** would still fail to disclose a translaminar fixation mechanism that secures the inferior implant to the inferior articular facet. According to the Examiner, the inferior implant is disclosed in **Soboleski** as element 16. The orifice 19 exists on a tongue extending from the element 14, which the Examiner calls the superior implant. Thus, any fixation mechanism interacting with the orifice 19 would secure what the Examiner calls the

superior implant, not what the Examiner calls the inferior implant. **Soboleski** does not disclose a translaminar fixation mechanism that interacts with an inferior implant.

For at least the reasons above, **Soboleski** does not disclose the claimed translaminar fixation mechanism and does not anticipate independent claim 1.

### ***Claims 14-17 and 19***

Claim 14 recites a facet implant comprising: superior implant having a fixation surface and a generally curved articulating surface, the superior implant being configured for placement on a resurfaced articulating surface of a superior articular facet; and an inferior implant having a fixation surface and a generally convex articulating surface, the inferior implant being configured for placement on a resurfaced articulating surface of an inferior articular facet, whereby the generally curved articulating surface of the superior implant and the generally convex articulating surface of the inferior implant being configured to interact.

As is discussed above with respect to claims 1, 2, 4-6 and 8-11, **Soboleski** discloses only a single implant, not a superior implant and an inferior implant. **Soboleski** also fails to disclose articulating surfaces that are configured to interact with one another. Instead, **Soboleski** identifies elements **14** and **16** surfaces on opposite sides of a single implant. Claim 14 is not anticipated.

### ***Claim 20***

Claim 20 recites facet implant comprising: a superior implant having a fixation surface and a generally curved articulating surface, the superior implant being



configured for placement on a resurfaced articulating surface of a superior articular facet; an inferior implant having a fixation surface and a generally convex articulating surface, the inferior implant being configured for placement on a resurfaced articulating surface of an inferior articular facet and for interacting with a translaminal screw, the articulating surface of the superior implant and the articulating surface of the inferior implant being configured to interact; and a translaminal fixation mechanism for securing the inferior implant to the inferior articular facet.

As discussed above with respect to claims 1, 2, 4-6 and 8-11, **Sobolesski** does not disclose both a superior implant and an inferior implant. Moreover **Sobolesski** also fails to disclose a translaminal fixation mechanism. Claim 20 is not anticipated.

#### ***Claims 41-44 and 46***

Claim 41 recites a facet implant comprising: superior implant means for providing an artificial articulating surface on a superior articular facet; inferior implant means for providing an artificial articulating surface on an inferior articular facet; and means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet.

Claim 41 invokes 35 U.S.C. § 112, ¶ 6 for each of the superior implant means, inferior implant means and means for securing the inferior implant means. The use of the word "implant" does not take either the superior implant means or the inferior implant means limitations out of the realm of § 112, ¶ 6. See, *Unidynamics Corp. v. Automatic Products Int'l, Ltd.*, 48 USPQ2d 1099 (Fed. Cir. 1998) ("spring means tending to keep the door closed" is a § 112, ¶ 6 "means" clause even though it recited some

structure ("spring"); *Overhead Door Corp. v. Chamberlain Group, Inc.*, 52 USPQ2d 1321 (Fed. Cir. 1999)("memory selection switch means being adapted to...." is subject to § 112, ¶ 6).

Accordingly, the structures corresponding to the means plus function elements of Claim 41 are as follows:<sup>12</sup>

| Claim element  | Corresponding Structure   |
|--|---|
| superior implant means for providing an artificial articulating surface on a superior articular facet                                | superior implant (102), including the variations thereof described on pages 5-10 of the specification |
| inferior implant means for providing an artificial articulating surface on an inferior articular facet                               | inferior implant (104), including the variations thereof described on pages 5-10 of the specification |
| means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet | translaminar fixation mechanism (106), including a screw, a bolt or a pin                             |

As explained in more detail above, **Soboleski** discloses only a single implant. Soboleski does not disclose means for providing artificial articulating surfaces on both the superior articular facet and the inferior articular facet.

Moreover, **Soboleski** does not disclose any structure capable of performing the claimed function of "securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet." Instead, as discussed in detail above, **Soboleski** discloses an orifice **19** for receiving a pedicle cortex screw. The device configuration described in **Soboleski** does not include means for securing anything to the inferior articular facet via a lamina connected to the inferior articular facet. Claim 41 is not anticipated.

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<sup>12</sup> Support for the corresponding structures is provided in more detail in Section V above.

***Claims 47-49, 51 and 52***

Claim 47 recites a facet implant comprising: a superior implant means for providing an artificial articulating surface on a superior articular facet, the superior implant means having a fixation surface and a generally curved articulating surface, the superior implant means being configured for placement on a resurfaced articulating surface of a superior articular facet such that the superior implant means primarily contacts only the articulating surface of the superior articulating facet; and an inferior implant means for providing an artificial articulating surface on an inferior articulating facet, the inferior implant means having a fixation surface and a generally convex articulating surface, the inferior implant means being configured for placement on a resurfaced articulating surface of an inferior articular facet such that the inferior implant means primarily contacts only the articulating surface of the inferior articulating facet; wherein the generally curved articulating surface of the superior implant means and the generally convex articulating surface of the inferior implant means are configured for articulating interaction.

Claim 47 is also subject to § 112, ¶ 6 for the same reasons set forth above in the discussion of claims 41-44 and 46. The structures corresponding to the superior implant means and the inferior implant means are the superior implant (102) and the inferior implant (104), respectively, including the variations thereof described on pages 5-10 of the specification.

Unlike claim 41, however, claim 47 requires the superior implant means and the inferior implant means to be configured for articulating interaction. As explained above

with reference to claims 1, 2, 4-6 and 8-11, **Soboleski** discloses a only a single implant and identifies elements 14 and 16 as surfaces on opposite sides of a single implant—

**not as surfaces configured for articulating interaction:**

The shim portion has two opposed surfaces, a first (lower) surface 14 engaging the superior articular surface of the superior facet 22, and a second (upper) surface 16 engaging the inferior articular surface of the corresponding inferior facet 32.<sup>13</sup>

Accordingly, **Soboleski** fails to disclose superior implant means and inferior implant means having articulating surfaces configured for articulating interaction. Claim 47 is not anticipated.

***Claims 53-55, 57 and 58***

Claim 53 recites a facet implant comprising: a superior implant means for providing an artificial articulating surface on a superior articular facet, the superior implant means having a fixation surface and a generally convex articulating surface, the superior implant means being configured for placement on a specifically prepared articulating surface of a superior articular facet such that the superior implant means primarily contacts only the articulating surface of the superior articulating facet; and an inferior implant means for providing an artificial articulating surface on an inferior articulating facet, the inferior implant means having a fixation surface and a generally curved articulating surface, the inferior implant means being configured for placement on a specifically prepared articulating surface of an inferior articular facet such that the inferior implant means primarily contacts only the articulating surface of the inferior

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<sup>13</sup> **Soboleski**, paragraph 0042.

articulating facet; wherein the generally curved articulating surface of the superior implant means and the generally convex articulating surface of the inferior implant means are configured for articulating interaction.

For the same reasons as set forth above with respect to claims 47-49, 51 and 52, claim 53 is not anticipated.

**B. Rejection of Claims 3, 12 and 13 under 35 U.S.C. § 103(a)**

Claims 3, 12 and 13 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over *Soboleski*. Claims 3, 12 and 13 depend from claim 1. The Examiner's rejection should be reversed for the same reasons set forth above with reference to claim 1.

**C. Rejection of Claims 7, 18, 45, 50 and 56 under 35 U.S.C. § 103(a)**

Claims 7, 18, 45, 50 and 56 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over *Soboleski* in view of *Yuan*. For the reasons discussed below, this rejection should be reversed.

***Claim 7***

Claim 7 depends from claim 1. The Examiner's rejection should be reversed for the same reasons set forth above with reference to claim 1.

***Claim 18***

Claim 18 depends from claim 14. The Examiner's rejection should be reversed for the same reasons set forth above with reference to claim 14.

***Claim 45***

Claim 45 depends from claim 41. The Examiner's rejection should be reversed for the same reasons set forth above with reference to claim 41.

***Claim 50***

Claim 50 depends from claim 47. The Examiner's rejection should be reversed for the same reasons set forth above with reference to claim 47.

***Claim 56***

Claim 56 depends from claim 53. The Examiner's rejection should be reversed for the same reasons set forth above with reference to claim 53.

**VIII. Conclusion**

In view of the foregoing, it is respectfully submitted that the claims are patentable over the applied art and that the final rejection should be reversed.

This brief is being submitted along with a payment by credit card in the amount of \$250.00 to cover the small entity fee set forth in 37 CFR 41.20(b).

Should a petition for an extension of time be necessary for the timely filing of this brief (or if such a petition has been made and an additional extension is necessary) petition is hereby made and the Commissioner is authorized to charge any fees to Deposit Account no. 18-0988, Order No. HORAP0101US.

Respectfully submitted,

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**IX. Claims Appendix**

Claims on Appeal

1. A facet implant comprising:
  - a superior implant having an articulating surface and a fixation surface and being configured for placement on a superior articular facet;
  - a inferior implant having an articulating surface and a fixation surface and being configured for placement on an inferior articular facet and for interacting with a translaminar fixation mechanism, whereby the articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact; and
  - a translaminar fixation mechanism for securing the inferior implant to the inferior articular facet.
2. The facet implant of claim 1 wherein the translaminar fixation mechanism comprises at least one of: a translaminar screw, a bolt or a fixation pin.
3. The facet implant of claim 2 wherein the inferior implant is configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees offset.
4. The facet implant of claim 1 wherein at least one of the superior implant or the inferior implant comprises a surface fixation mechanism.
5. The facet implant of claim 4 wherein the surface fixation mechanism comprises at least one of: one or more pegs, one or more pips, ridges, or one or more screws.
6. The facet implant of claim 4 wherein the surface fixation mechanism comprises multiple regions wherein each of the regions has at least one ridge oriented in a different direction than the ridges of the other regions.



7. The facet implant of claim 1 wherein at least one of the fixation surfaces of the inferior implant and the superior implant has at least one of: a porous coating, a porous onlay material, a biologic coating, or a surface treatment.

8. The facet implant of claim 1 wherein the articulating surface of the superior implant is generally curved.

9. The facet implant of claim 1 wherein the fixation surface of the superior implant is generally curved.

10. The facet implant of claim 1 wherein the articulating surface of the inferior implant is generally curved.

11. The facet implant of claim 1 wherein at least one of the articulating surfaces of the inferior implant and the superior implant is composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

12. The facet implant of claim 1 wherein the inferior implant ranges from about 2 mm thick to about 15 mm thick.

13. The facet implant of claim 1 wherein the superior implant ranges from about 2 mm thick to about 15 mm thick.

14. A facet implant comprising:

a superior implant having a fixation surface and a generally curved articulating surface, the superior implant being configured for placement on a resurfaced articulating surface of a superior articular facet; and

an inferior implant having a fixation surface and a generally convex articulating surface, the inferior implant being configured for placement on a resurfaced articulating surface of an inferior articular facet, whereby the generally

curved articulating surface of the superior implant and the generally convex articulating surface of the inferior implant being configured to interact.

15. The facet implant of claim 14 wherein at least one of the superior implant and the inferior implant comprises a surface fixation mechanism.

16. The facet implant of claim 15 wherein the surface fixation mechanism comprises at least one of: one or more pegs, one or more pips, ridges, or one or more screws.

17. The facet implant of claim 15 wherein the surface fixation mechanism comprises multiple regions wherein each of the regions has at least one ridge oriented in a different direction than the ridges of the other regions.

18. The facet implant of claim 14 wherein at least one of the fixation surfaces of the inferior implant and the superior implant has at least one of: a porous coating, a porous onlay material, a biologic coating, or a surface treated to facilitate bone ingrowth.

19. The facet implant of claim 14 wherein at least one of the articulating surfaces of the inferior implant and the superior implant is composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

20. A facet implant comprising:

a superior implant having a fixation surface and a generally curved articulating surface, the superior implant being configured for placement on a resurfaced articulating surface of a superior articular facet;

a inferior implant having a fixation surface and a generally convex articulating surface, the inferior implant being configured for placement on a resurfaced articulating surface of an inferior articular facet and for interacting with a translaminal screw, the articulating surface of the superior implant and the articulating surface of the inferior implant being configured to interact; and

a translaminar fixation mechanism for securing the inferior implant to the inferior articular facet.

41. A facet implant comprising:

superior implant means for providing an artificial articulating surface on a superior articular facet;

inferior implant means for providing an artificial articulating surface on an inferior articular facet; and

means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet.

42. The facet implant of claim 41 wherein the means for securing the inferior implant means to the inferior articular facet comprises at least one of: a screw, a bolt or a fixation pin.

43. The facet implant of claim 41 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises a surface fixation mechanism.

44. The facet implant of claim 43 wherein the surface fixation mechanism comprises at least one of: one or more pegs, one or more pips, ridges, or one or more screws.

45. The facet implant of claim 41 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises a fixation surface having at least one of: a porous coating, a porous onlay material, a biologic coating, or a surface treatment.

46. The facet implant of claim 41 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises an articulating surface composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

47. A facet implant comprising:

a superior implant means for providing an artificial articulating surface on a superior articular facet, the superior implant means having a fixation surface and a generally curved articulating surface, the superior implant means being configured for placement on a resurfaced articulating surface of a superior articular facet such that the superior implant means primarily contacts only the articulating surface of the superior articulating facet; and

an inferior implant means for providing an artificial articulating surface on an inferior articulating facet, the inferior implant means having a fixation surface and a generally convex articulating surface, the inferior implant means being configured for placement on a resurfaced articulating surface of an inferior articular facet such that the inferior implant means primarily contacts only the articulating surface of the inferior articulating facet;

wherein the generally curved articulating surface of the superior implant means and the generally convex articulating surface of the inferior implant means are configured for articulating interaction.

48. The facet implant of claim 47 wherein at least one of superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articulating facet comprises a surface fixation mechanism.

49. The facet implant of claim 48 wherein the surface fixation mechanism comprises at least one of: one or more pegs, one or more pips, ridges, or one or more screws.

50. The facet implant of claim 47 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises a fixation surface having at least one of: a porous coating, a porous onlay material, a biologic coating, or a surface treatment.

51. The facet implant of claim 47 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises an articulating surface composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

52. The facet implant of claim 47 further comprising means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet.

53. A facet implant comprising:

a superior implant means for providing an artificial articulating surface on a superior articular facet, the superior implant means having a fixation surface and a generally convex articulating surface, the superior implant means being configured for placement on a specifically prepared articulating surface of a superior articular facet such that the superior implant means primarily contacts only the articulating surface of the superior articulating facet; and

an inferior implant means for providing an artificial articulating surface on an inferior articulating facet, the inferior implant means having a fixation surface and a generally curved articulating surface, the inferior implant means being configured for placement on a specifically prepared articulating surface of an inferior articular facet such that the inferior implant means primarily contacts only the articulating surface of the inferior articulating facet;

wherein the generally curved articulating surface of the superior implant means and the generally convex articulating surface of the inferior implant means are configured for articulating interaction.

54. The facet implant of claim 53 wherein at least one of superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articulating facet comprises a surface fixation mechanism.

55. The facet implant of claim 54 wherein the surface fixation mechanism comprises at least one of: one or more pegs, one or more pips, ridges, or one or more screws.

56. The facet implant of claim 53 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises a fixation surface having at least one of: a porous coating, a porous onlay material, a biologic coating, or a surface treatment.

57. The facet implant of claim 53 wherein at least one of the superior implant means for providing an artificial articulating surface on a superior articular facet or the inferior implant means for providing an artificial articulating surface on an inferior articular facet comprises an articulating surface composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

58. The facet implant of claim 53 further comprising means for securing the inferior implant means to the inferior articular facet via a lamina connected to the inferior articular facet.

**X. Evidence Appendix**

None.

**XI. Related Proceedings Appendix**

None.